

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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| Complete if Known    |                  |
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| Application Number   | 10/609,301       |
| Filing Date          | June 27, 2003    |
| Confirmation Number  | 8048             |
| First Named Inventor | Robert A. Holton |
| Group Art Unit       | 1625             |
| Examiner Name        | TRINH            |
| Attorney Docket No.  | FSUM 10463.21    |

## U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | U.S. Patent Document |                                      | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document<br>MM-DD-YYYY |
|--------------------|-----------------------|----------------------|--------------------------------------|---|---|
|                    |                       | Number               | Kind Code <sup>2</sup><br>(if known) |   |   |
| BT                 | 1                     | 4,960,790            |                                      | Stella et al.                                   | 10-02-1990  |
| BT                 | 2                     | 5,175,315            |                                      | Holton  | 12-29-1992  |
| BT                 | 3                     | 5,227,400            |                                      | Holton et al.                                   | 07-13-1993  |
| BT                 | 4                     | 5,243,045            |                                      | Holton et al.                                   | 09-07-1993  |
| BT                 | 5                     | 5,283,253            |                                      | Holton et al.                                   | 02-01-1994  |
| BT                 | 6                     | 5,350,866            |                                      | Holton et al.                                   | 09-27-1994  |
| BT                 | 7                     | 5,430,160            |                                      | Holton  | 07-04-1995  |
| BT                 | 8                     | 5,556,877            |                                      | Bouchard et al.                                 | 09-17-1996  |
| BT                 | 9                     | 5,556,878            |                                      | Kelley et al.                                   | 09-17-1996  |
| BT                 | 10                    | 5,567,614            |                                      | Patel et al.                                    | 10-22-1996  |
| BT                 | 11                    | 5,614,645            |                                      | Kingston et al.                                 | 03-25-1997  |
| BT                 | 12                    | 5,714,513            |                                      | Holton et al.                                   | 02-03-1998  |
| BT                 | 13                    | 5,721,268            |                                      | Holton et al.                                   | 02-24-1998  |
| BT                 | 14                    | 5,756,536            |                                      | Chen et al.                                     | 05-26-1998  |

Examiner Signature

Date Considered

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|    |    |           |                |            |
|----|----|-----------|----------------|------------|
| DT | 15 | 5,767,297 | Mandai et al.  | 06-16-1998 |
| DT | 16 | 5,780,653 | Tao et al.     | 07-14-1998 |
| DT | 17 | 5,811,452 | Ojima et al.   | 09-22-1998 |
| DT | 18 | 5,879,929 | Patel          | 03-09-1999 |
| DT | 19 | 5,912,264 | Wittman et al. | 06-15-1999 |
| DT | 20 | 5,939,561 | Bourzat et al. | 08-17-1999 |

## FOREIGN PATENT DOCUMENTS

| Examiner Initials <sup>1</sup> | Cite No. <sup>1</sup> | Foreign Patent Document |                     |                                   | Name of Patentee or Applicant of Cited Document         | Date of Publication of Cited Document MM-DD-YYYY | T <sup>6</sup> |
|--------------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|--|----------------|
|                                |                       | Office                  | Number <sup>4</sup> | Kind Code <sup>2</sup> (if known) |   |  |                |
| DT                             | 21                    | EP                      | 0 558 959           | B1                                | Bristol-Myers Squibb Co.                                | 09-08-1993                                       |                |
| DT                             | 22                    | EP                      | 0 629 701           | B1                                | Bristol-Myers Squibb Co.                                | 12-21-1994                                       |                |
| DT                             | 23                    | EP                      | 0 687 259           | B1                                | Rhone-Poulenc Rorer                                     | 12-20-1995                                       |                |
| DT                             | 24                    | EP                      | 0 882 732           | A1                                | Ensulko Sugar Refining Co., Ltd.                        | 12-09-1998                                       |                |
| DT                             | 25                    | WO                      | 93/18018            | A1                                | University of Florida                                   | 09-16-1993                                       |                |
| DT                             | 26                    | WO                      | 94/20484            | A1                                | Rhone-Poulenc Rorer S.A.                                | 09-15-1994                                       |                |
| DT                             | 27                    | WO                      | 95/11241            | A1                                | Rhone-Poulenc Rorer S.A.                                | 04-27-1995                                       |                |
| DT                             | 28                    | WO                      | 96/13495            | A1                                | The Research Foundation of State University of New York | 05-09-1996                                       |                |
| Examiner Signature             |                       | <i>2</i>                |                     | Date Considered                   | 12-03   |  |                |

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|----|----|----|----------|----|--|------------|
| ST | 29 | WO | 97/09979 | A1 | Florida State University                           | 03-20-1997 |
| BT | 30 | WO | 97/16200 | A1 | Merck & Co., Inc.                                  | 05-09-1997 |
| ST | 31 | WO | 97/42181 | A1 | Florida State University                           | 11-13-1997 |
| BT | 32 | WO | 98/02426 | A1 | Kabushiki Kaisha Yakult Honsah                     | 01-22-1998 |
| ST | 33 | WO | 99/09021 | A1 | Florida State University                           | 02-25-1999 |
| BT | 34 | WO | 01/57013 | A1 | Florida State University Research Foundation, Inc. | 08-09-2001 |

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

|                    |                       |  |                |
|--------------------|-----------------------|--|----------------|
| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>6</sup> |
| ST                 | 35                    | GUERITTE-VOEGELEIN et al. "Relationships between the Structure of Taxol Analogues and Their Antimitotic Activity" Journal of Medicinal Chemistry, Vol. 34, No. 3 (1991) pp. 992-998.   |                |
| BT                 | 36                    | KANT et al. "A Chemoselective Approach to Functionalize the C-10 Position of 10-Deacetylbaccatin III. Synthesis and Biological Properties of Novel C-10 Taxol Analogues" Tetrahedron Letters, Vol. 35, No. 30 (1994) pp. 5543-5546.                            |                |
| ST                 | 37                    | KINGSTON et al. "The Chemistry of Taxol, A Clinically Useful Anticancer Agent" J. of Natural Products, Vol. 53, No. 1 (1990) pp. 1-12.   |                |
| BT                 | 38                    | MELLADO et al. "Preparation and Biological Activity of Taxol Acetates" Biochemical and Biophysical Research Communications Vol. 124, No. 2 (1984) pp. 329-336.   |                |
| BT                 | 39                    | PULICANI et al. "Direct Access to 2-Debenzoyl Taxoids by Electrochemistry, Synthesis of 2-Modified Docetaxel Analogs" Tetrahedron Letters, Vol. 35 No. 52 (1994) pp. 9717-9720.  |                |

|                    |  |                 |       |
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| 40 | RAO et al. "Synthesis and Evaluation of Some 10-Mono- and 2',10-Diesters of 10-Deacetylpaclitaxel" Journal of Medicinal Chemistry, Vol. 38, No. 17 (1995) pp. 3411-3414.   |
| 41 | SAMARANAYAKE et al. "Modified TAXols. 5. Reaction of Taxol with Electrophilic Reagents and Preparation of a Rearranged Taxol Derivative with Tubulin Assembly Activity" J. Org. Chem., Vol. 56, No. 17 (1991) pp. 5114-5119.   |
| 42 | STRAUBINGER et al. "Pharmacology and Antitumor Effect of Novel Paclitaxel Formulations" Chapter 8, Edited by G. Georg et al., Taxane Anticancer Agents, Basic Science and Current Status, ACS Symposium Series 583, 207th National Meeting of the American Chemical Society, San Diego, CA (1994) pp. 111-123. |
| 43 | SUFFNESS "Chapter 32. Taxol: From Discovery to Therapeutic Use" Annual Reports in Medicinal Chemistry, Vol. 28 (1993) pp. 305-314.   |
| 44 | International Search Report for analogous PCT Application No. PCT/US01/03553 dated June 11, 2001.  |

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